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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/316,199	05/21/1999	Michael J McCluskie	C1040/7006HC	7506

7590 10/21/2011  
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EXAMINER
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POPA, ILEANA

ART UNIT	PAPER NUMBER
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1633

MAIL DATE	DELIVERY MODE
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10/21/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Notice of Non-Compliant  
Amendment (37 CFR 1.121)**

Application No.

09/316,199

Examiner

ILEANA POPA

Applicant(s)

MCCLUSKIE ET AL.

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

The amendment document filed on 08/01/2011 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121 or 1.4. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
- ☐ A. Amended paragraph(s) do not include markings.
  - ☐ B. New paragraph(s) should not be underlined.
  - ☐ C. Other \_\_\_\_\_.
- ☐ 2. Abstract:
- ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
  - ☐ B. Other \_\_\_\_\_.
- ☐ 3. Amendments to the drawings:
- ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
  - ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
  - ☐ C. Other \_\_\_\_\_.
- ☐ 4. Amendments to the claims:
- ☐ A. A complete listing of all of the claims is not present.
  - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
  - ☐ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
  - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
  - ☒ E. Other: See Continuation Sheet.
- ☐ 5. Other (e.g., the amendment is unsigned or not signed in accordance with 37 CFR 1.4):  
\_\_\_\_\_

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714.

TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:

1. Applicant is given **no new time period** if the non-compliant amendment is an after-final amendment or an amendment filed after allowance. If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted.
2. Applicant is given **one month**, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the correction, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a *Quayle* action. If any of above boxes 1. to 4. are checked, the correction required is only the **corrected section** of the non-compliant amendment in compliance with 37 CFR 1.121.

**Extensions of time** are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

**Failure to timely respond** to this notice will result in:

**Abandonment** of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or

**Non-entry** of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.

/Ileana Popa/  
Primary Examiner, Art Unit 1633

Continuation of 4(e) Other: The amendment filed on 11/23/2010 canceling all claims drawn to the elected invention and presenting only claims drawn to a non-elected invention is non-responsive (MPEP § 821.03). The new claims are not readable on the elected invention because they are drawn to methods which are independent and distinct from the elected method. The elected invention is drawn to a specific immunization protocol, i.e., mucosal administration of an antigen and a CpG, followed by boosting with the CpG via any route. The new claims introduce new independent and distinct immunization protocols, specifically: (i) mucosal administration of an antigen and a CpG, followed by systemic boosting with the antigen; and (ii) systemic administration of an antigen, followed by mucosal boosting with the antigen and a CpG.

The argument that the examiner has mischaracterized the elected invention is not found persuasive. The elected invention is drawn to mucosal administration of CpG and antigen (claim 1), followed by boosting with CpG by any route (claim 27), an immunization protocol which is distinct from the immunization protocol recited in claims 147-166, which are drawn to mucosal administration of an antigen and CpG, followed by systemic boosting with the antigen (claim 147); and (ii) systemic administration of an antigen, followed by mucosal boosting with the antigen and CpG (claim 160). Thus, claims 147 and 160 and their dependent claims are directed to a non-elected invention. Had these claims been originally presented, a restriction of the invention recited in the claims would have been requested.

Since the above-mentioned amendment appears to be a bona fide attempt to reply, applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS, whichever is longer, from the mailing date of this notice within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD UNDER 37 CFR 1.136(a) ARE AVAILABLE.